

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bäckström et al. Art Unit : Unknown
Serial No. : Examiner : Unknown
Filed : Herewith
Title : COMPOSITIONS FOR INHALATION

MAIL STOP PATENT APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 08/736,267, filed on October 24, 1996, which claims priority from Swedish Patent Application No. 9400371-2, filed on February 4, 1994, which claims priority from Swedish Patent Application No. 9302198-8, filed June 24, 1993. The references cited on the attached form were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application.

This statement is being filed with the application. Please apply any charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 06275-004003.

Respectfully submitted,

Date: 3/3/2004



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Substitute Form PTO-1449 (Modified) Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
	Applicant Bäckström et al.		
	Filing Date	Group Art Unit	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2,992,645	07/18/61	Fowler			
	AB	3,014,844	12/26/2001	Thiel			
	AC	3,671,625	06/1972	Altounyan			
	AD	3,911,138	10/07/1975	Clark	424	352	
	AE	4,232,002	11/1980	Nogrady			
	AF	4,462,983	07/1984	Azria			
	AG	4,524,769	06/25/1985	Wetterlin	128	203.15	
	AH	4,534,345	08/13/1985	Wetterlin	128	203.15	
	AI	4,537,772	08/1985	Alexander			
	AJ	4,548,922	10/22/1985	Carey et al.	514	4	
	AK	4,613,500	09/23/1986	Suzuki et al.	424	85.4	
	AL	4,668,218	05/26/2987	Virtanen	604	58	
	AM	4,690,952	09/01/1987	Kagatani et al.	514	11	
	AN	4,731,360	03/1988	Alexander			
	AO	4,746,508	05/24/1988	Carey et al.	424	88	
	AP	4,788,221	11/29/1988	Kagatani et al.	514	12	
	AQ	4,847,298	04/11/1989	Alexander			
	AR	4,895,719	01/23/1990	Radhakrishnan			
	AS	4,900,730	02/13/1990	Miyauchi	514	12	
	AT	4,907,583	03/13/1990	Wetterlin et al.	128	203.15	
	AU	4,914,084	04/03/1990	Ecanow	514	006	
	AV	4,920,061	04/24/1990	Poynton	436	526	
	AW	4,926,852	05/22/90	Zoltan et al.	128	200.23	
	AX	4,959,358	09/28/1998	Carey et al.	514	171	
	AY	4,963,367	10/16/1990	Ecanow			

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AZ	4,994,439	02/19/1991	Longnecker			
	AAA	5,006,343	04/09/1991	Benson			
	ABB	5,011,678	04/30/1991	Wang			
	ACC	5,118,494	06/02/1992	Schultz			
	ADD	5,122,127	06/16/1992	Stanley			
	AEE	5,122,376	06/16/1992	Aliverti			
	AFF	5,179,079	01/12/1993	Hansen et al.	514	4	
	AGG	5,192,548	03/09/1993	Velasquez et al.			
	AHH	5,200,393	04/06/1993	Weiner			
	AII	5,202,129	04/13/1993	Samejima et al.	424	489	
	AJJ	5,254,330	10/19/1993	Ganderton et al.			
	AKK	5,260,306	11/09/1993	Boardman et al.			
	ALL	5,284,656	02/08/1994	Platz et al.	424	435	
	AMM	5,288,498	02/22/1994	Stanley et al.			
	ANN	5,320,094	06/14/1994	Laube et al.	128	203.12	
	AOO	5,341,800	08/30/1994	Clark et al.	128	203.15	
	APP	5,348,730	09/20/1994	Greenleaf			
	AQQ	5,349,947	09/27/1994	Newhouse et al.	128	203.21	
	ARR	5,352,461	10/04/1994	Feldstein et al.	424	493	
	ASS	5,354,562	10/11/1994	Platz et al.	424	489	
	ATT	5,364,838	11/15/1994	Rubsamen	514	3	
	AUU	5,376,359	12/1994	Johnson			
	AVV	5,376,386	12/27/1994	Ganderton et al.			
	AWW	5,384,133	01/24/1995	Boyes et al.			
	AXX	5,384,133	01/24/1995	Bäckström et al.			

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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AYY	5,419,315	05/30/1995	Rubsamen	128	200.14	
	AZZ	5,437,271	08/01/1995	Hodson et al.			
	BA	5,437,271	08/01/1995	Bäckström et al.			
	BB	5,451,569	09/19/1995	Wong et al.	514	3	
	BC	5,458,135	10/17/1995	Patton et al.	128	200.14	
	BD	5,474,759	12/1995	Fassberg et al.			
	BE	5,482,032	01/09/1996	Smith et al.			
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	BG	5,506,203 C1	04/1996	Bäckström et al.			
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	BJ	5,607,915	03/04/1997	Patton	514	12	
	BK	5,658,878	08/1997	Bäckström et al.			
	BL	5,661,130	08/26/1997	Meezan et al.	514	25	
	BM	5,707,644	01/13/1998	Jillem			
	BN	5,730,969	03/24/1998	Hora et al.	424	85.1	
	BO	5,747,445	05/1988	Bäckström et al.			
	BP	5,814,607	09/29/1998	Patton	514	12	
	BQ	5,830,853	11/1998	Bäckström et al.			
	BR	5,858,968	01/1999	Weiner et al.			
	BS	5,952,008	09/1999	Bäckström et al.			
	BT	5,997,848	12/07/1999	Patton et al.	424	46	
	BU	6,004,574	12/1999	Bäckström et al.			
	BV	6,051,256	04/18/2000	Platz et al.	424	489	
	BW	6,165,976	12/2000	Bäckström et al.			

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	BX	6,306,440	10/2001	Bäckström et al.			
	BY	6,436,902 B1	8/2002	Bäckström et al.			
	BZ	6,524,557	02/2003	Bäckström et al.			
	BAA	6,534,557					
	BBB	20030064928 A1		Bäckström et al.			
	BCC	08/601,005					
	BDD	08/736,267					
	BEE	08/906,825					
	BFF	08/960,093					
	BGG	09/072,717					
	BHH	09/158,554					
	BII	09/383,590					
	BJJ	09/665,585					
	BKK	09/731,429					
	BLL	09/783,189					
	BMM	10/224,522					
	BNN	10/401,157					
	BOO	10/401,181					

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	BPP	0 023 359	07/29/1980	Europe				
	BQQ	0 055 041	12/03/1981	Europe				
	BRR	0 122 036	10/17/1984	Europe				
	BSS	0 128 831	12/19/1984	Europe				
	BTT	0 133 252 A2	02/1985	Europe				

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Foreign Patent Documents or Published Foreign Patent Applications								
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							Yes	No
	BUU	0 200 383	04/07/1986	Europe				
	BVV	0 225 189	11/28/1986	Europe				
	BWW	0 272 0978	06/22/1988	Europe				
	BXX	0 312 052 A1	10/1987	Europe				
	BYV	0 360 340	03/28/1990	Europe				
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	CA	0 383 751	09/1994	Europe				
	CB	0 455 463	11/06/1991	Europe				
	CC	1,242,211	08/11/1971	United Kingdom				
	CD	1,520,247	08/02/1978	United Kingdom				
	CE	1,527,605	10/04/1976	United Kingdom				
	CF	1,569,611	06/18/1980	United Kingdom				
	CG	2,115,065	06/11/1993	Canada				
	CH	43556/93	01/04/1994	Australia				
	CI	8 007 820-7	11/17/1986	Sweden				
	CJ	9 302 198-8	06/1993	Sweden				
	CK	9 400 371-2	02/1994	Sweden				
	CL	DD 261 096 A1	10/19/1988	Germany				
	CM	GB 837,465	06/15/1960	Great Britain				
	CN	Hei 4-149126	05/22/1992	Japan				
	CO	Hei 4-41421	02/12/1992	Japan				
	CP	JP1117825	02/10/1987	Japan				
	CQ	JP4041421	06/1990	Japan				
	CR	JP4149126	1992	Japan				
	CS	JP632932	07/01/1988	Japan				
	CT	WO 87/05213 A1	09/1987	WIPO				
	CU	WO 88/09163	12/01/1998	PCT				

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	CV	WO 90/04962	05/17/1990	PCT				
	CW	WO 90/07333	04/12/1990	PCT				
	CX	WO 91/16038	10/31/1991	PCT				
	CY	WO 91/16882	11/14/1991	PCT				
	CZ	WO 91/16929	11/14/1991	PCT				
	CAA	WO 91/18091 A1	11/19/1991	PCT				
	CBB	WO 92/04069	03/19/1992	PCT				
	CCC	WO 92/06704	04/30/1992	PCT				
	CDD	WO 92/08446	05/29/1992	PCT				
	CEE	WO 93/25198	12/23/1993	PCT				
	CFE	WO 94/07514	04/14/1994	PCT				
	CGG	WO 94/22461	10/13/1994	PCT				
	CHH	WO 95/00128	01/1995	PCT				
	CII	WO 95/00151	01/05/1995	PCT				
	CJJ	WO 96/19206	06/1996	PCT				
	CKK	WO 96/19207	06/1996	PCT				
	CLL	WO 97/10850	03/27/1997	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	CMM	"Diabetes Mellitus" Ch. VI in <i>Scientific American Medicine</i> , Scientific American, Inc. (1993)
	CNN	Allenby et al. "The Absorption of Insulin Across the Respiratory Tract of the Guinea-Pig (U)" <i>The Aerosol Society, Fourth Annual Conference</i> 129-134 (1990)
	COO	Almer et al. <i>Diabetes Research and Clin. Pract.</i> 5:s163 (1988)
	CPP	Aungst et al, "Comparison of Nasal...", <i>The Journal of Pharmacology and Experimental Therapeutics</i> 244:23-27 (1987)
	CQQ	Aungst et al. "Comparison of the Effects of Various Transmucosal Absorption Promoters on Buccal Insulin Delivery" <i>Int. J. Pharm.</i> 53(3):227-235 (1989)
	CRR	Barbaud <i>Clinical Reviews in Allergy and Immunology</i> 13(3):253-263 (1995)

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Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	CSS	Björk et al. "Degradable Starch Microspheres as a Nasal Delivery System for Insulin" <i>Int. J. Pharm.</i> 47:233-238 (1988)
	CTT	Bjork et al., "Characterization of degradable starch..." <i>Int. J. Pharmaceutics</i> 62:187-192 (1990)
	CUU	Björk "Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy" <i>Acta Univ. Uppsala</i> 103 (1993)
	CVV	Björk "Starch Microspheres as a Nasal Delivery System for Drugs" <i>Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy</i> 103 (1993)
	CWW	Brange et al. "Monomeric Insulins and their Experimental and Clinical Implications" <i>Diabetes Care</i> 13:923-954 (1990)
	CXX	Byron et al., "Drug Delivery via the Respiratory..." <i>Journal of Aerosol Medicine</i> 7:49-75 (1994)
	CYY	Chandler et al. "Nasal Absorption Rats. II. Effect of Enhancers on Insulin Absorption and Nasal Histology" <i>Int. J. Pharmaceutics</i> 76:61-70 (1991)
	CZZ	Chien et al. "Intranasal Drug Delivery for Systemic Medications" <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> 4:67-194 (1987)
	DA	Chien et al., "Potential Developments in..." <i>Drug Development and Industrial Pharmacy</i> 15(10):1601-1634 (1989)
	DB	Colthorpe et al., "The Pharmacokinetics..." <i>Pharmaceutical Research</i> 9(6):764-768 (1992)
	DC	Cutie et al. "The Role of the Dispersing Agents in Inhalation and Intranasal Aerosol Suspensions" <i>Aerosol. Age</i> 30:52-54 (1985)
	DD	Dahlbäck et al. "Regional Administration of Drugs to the Rabbit Respiratory Tract, Effects on Absorption" <i>J. Aerosol. Medicine</i> 1:222-223 (1988)
	DE	Damsay et al. <i>Diabetes Res. and Clin. Pract.</i> 5:s163 (1988)
	DF	Dempster et al. "Anabolic Actions of Parathyroid Hormone on Bone" <i>Endocrine Reviews</i> 14: 690-709 (1993).
	DG	Edman et al. "Routes of Delivery: Case Studies" <i>Advanced Drug Delivery Reviews</i> 8:165-177 (1992)
	DH	Elliott et al. "Parenteral absorption of insulin..." <i>Aust. Paediatr. J.</i> 23:293-297 (1987)
	DI	Eppstein et al. "Alternative Delivery Systems for Peptides and Proteins as Drugs" <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> 5:99-139 (1988)
	DJ	Goni et al., "Palmitoylcarnitine, a surface-active metabolite" <i>FEBS Lett.</i> 390:1-5 (1996)
	DK	Gordon et al. "Nasal Absorption of Insulin: Enhancement by Hydrophobic Bile Salts" <i>Proc. Natl. Acad. Sci. USA</i> 82:7419-7423 (1985)
	DL	Hirai et al. "Effect of Surfactants on the Nasal Absorption of Insulin in Rats" <i>Int. J. Pharmaceutics</i> 9:165-172 (1981)
	DM	Hoover et al, "Peptides are Better," <i>Pharmaceutical Research</i> 9(8):1103-1106 (1992)
	DN	Igawa et al. "Effect of Absorption Promoters in Intranasal Administration of Human Fibroblast Interferon as a Powder Dosage Form in Rabbits" <i>Chem. Pharm. Bull.</i> 37:418-421 (1989)
	DO	Jacobs et al. "The Pharmacodynamics and..." <i>Diabetes</i> 42:1649-1655 (1993)

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	DP	Jaegfeldt et al. "Particle size distribution from different modifications of Turbuhaler" <i>Proceedings of an international workshop on a new inhaler</i> 21-22:90-99 (1987)
	DQ	Jones "Pulmonary Absorption of Insulin" <i>Ph.D. Thesis, Welsh School of Pharmacy, University of Wales, United Kingdom</i> (1998)
	DR	Kalinkova <i>International Journal of Pharmaceutics</i> 187(1):1-15 (1999)
	DS	Köhler et al. "Pulmonary Administration..." <i>Diabetes</i> 33:75A (1984)
	DT	Köhler et al. "Non radioactive procedure for the measurement of lung permeability: inhalation of insulin" <i>Atemw.-Lungenkrkh., Jahrgang</i> 13:230-232 (1987)
	DU	Köhler "Aerosols for Systemic Treatment" <i>Lung Supp</i> 1:677-684 (1990)
	DV	Komada et al. "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" <i>J. Pharm. Sci.</i> 83:863-867 (1994)
	DW	Lasker "The Diabetes Control and Complications Trial" <i>N.Engl. J. Med.</i> 329:1035-1036 (1993)
	DX	Laube et al. "Preliminary Study of the Efficacy of Insulin Aerosol Delivered by Oral Inhalation in Diabetic Patients" <i>JAMA</i> 269:2106-2109 (1993)
	DY	Lecluyse et al. "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa" <i>J. Pharmacol. Exp. Ther.</i> 265(2):955-962 (1993)
	DZ	Lee et al. "Development of an Aerosol Dosage Form Containing Insulin" <i>J. Pharmaceutical Sciences</i> 65(4):567-574 (1976)
	DAA	Lee et al. <i>American Chemical Society</i> 301-309 (1987)
	DBB	Lee et al. "Intranasal Bioavailability of Insulin Powder Formulations: Effect of Permeation Enhancer-to-Protein Ratio" <i>J. Pharm. Sci.</i> 80:725-729 (1991)
	DCC	Lee et al. "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" <i>Critical Rev. Therapeut. Drug Carrier Systems</i> 8:191-192 (1991)
	DDD	Li et al. "Effect of a ..." <i>Eur. J. Pharm. Biopharm.</i> 39:216-221 (1993)
	DEE	Liu et al. "Pulmonary Delivery of Free..." <i>Pharmaceutical Research</i> 10:228-232 (1993)
	DFE	Longnecker et al. "Effects of Sodium Taurodi hydrofusidate on Nasal Absorption of Insulin in Sheep" <i>J. Pharm. Sci.</i> 76(5):351-355 (1987)
	DGG	Mishima et al. "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats" <i>J. Pharma.</i> 10:624-631 (1987)
	DHH	Mizgala et al. "Renal Handling of Phosphate" <i>Physiological Reviews</i> 65(2):431-466 (1985)
	DII	Morita et al. "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs with Different Molecular Weights" <i>Biol. Pharm. Bull.</i> 16:269-262 (1993)
	DJJ	Moses et al. "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" <i>Diabetes</i> 32:1040-1047 (1983)
	DKK	Nagai et al. "Powder Dosage Form of Insulin for Nasal Administration" <i>J. Controlled Release</i> 1:15-22 (1984)
	DLL	Nagano et al. "New Method of Insulin..." <i>Jikeikai Med. J.</i> 32:503-506 (1985)

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	DMM	Newman, "Chapter 9: Therapeutic aerosols" <i>Aerosols and the Lung: Clinical and Experimental Aspects</i> , Butterworth & Co., United Kingdom (1984)
	DNN	O'Hagan et al. "Absorption of Peptides and Proteins from the Respiratory Tract and the Potential for Development of Locally Administered Vaccine" <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> 7:35-97 (1990)
	DOO	Okumura et al. "Intratracheal delivery of insulin absorption from solution and aerosol by rat lung" <i>International Journal of Pharmaceutics</i> 88:63-73 (1992)
	DPP	Olanoff et al. "Method to Enhance Intranasal Peptide Delivery" <i>Controlled-Release Technology Pharmaceutical Applications</i>
	DQQ	Patton et al. "(D) Routes of Delivery: Case Studies" <i>Advanced Drug Delivery Reviews</i> 8:179-196 (1992)
	DRR	Patton et al. "Bioavailability of Pulmonary Delivered Peptides and Proteins: α -interferon, Calcitonins and Parathyroid Hormones" <i>Journal of Controlled Release</i> 28:79-85 (1994)
	DSS	Pifferi <i>FARMACO</i> 54(1-2):1-14 (1999)
	DTT	Pontiroli et al. "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: a Comparison of Powders and Spray Solutions and of Different Enhancing Agents" <i>Eur. J. Clin. Pharmacol.</i> 37:427-430 (1989)
	DUU	Remington's Pharmaceutical Science, 18 th Edition, p. 1079 (1990)
	DVV	Ruin "Diabetics May Not Need Their Insulin Shots" <i>Sydsvenska (Dagbladet)</i> (1989)
	DWW	Sakr "A new approach for insulin..." <i>International Journal of Pharmaceutics</i> 86:1-7 (1992)
	DXX	Salzman et al., "Intranasal Aerosolized Insulin Mixed-Meal Studies and Long-term Use in Type I Diabetes" <i>The New England Journal of Medicine</i> 312:1078-1084 (1985)
	DYY	Schipper et al. "Nasal Insulin Delivery with Dimethyl- β -Cyclodextrin as an Absorption Enhancer in Rabbits: Powder More Effective than Liquid Formulations" <i>Pharmaceutical Research</i> 10:682-686 (1993)
	DZZ	Schluter et al. "Pulmonary Administration... Type 1 Diabetics" Abstract #298, <i>Diabetes</i> , 33 (Supplement): 75A (1984)
	EA	Selam et al. "Devices for Insulin Administration" <i>Diabetes Care</i> 13:955-979 (1990)
	EB	The Diabetes Control and Complications Trial Research Group "The Effect of Intensive Treatment of Diabetes on the Development... Complications in Insulin-Dependent Diabetes" <i>N. Engl. J. Med.</i> 329:977-986 (1993)
	EC	Timsina et al. "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers" <i>Int. J. Pharmaceutics</i> 101:1-13 (1994)
	ED	Touitou et al. "Targeted Enteral Delivery of Insulin to Rats" <i>Int. J. Pharm.</i> 30(2-3):95-100 (1986)
	EE	Wang et al. <i>Parenteral Science and Technology</i> , 42(2S):S4-S26 (1988)
	EF	Wearly "Recent Progress in Protein and Peptide Delivery by Noninvasive Routes" <i>Critical Rev. Therapeut. Drug Carrier Systems</i> 8:331-394 (1991)
	EG	Wetterlin "Turbuhaler: A New Powder Inhaler for Administration of Drugs to the Airways" <i>Pharmaceutical Research</i> 5:506-508 (1988).

Examiner Signature	Date Considered
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-004003	Application No.
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Bäckström et al.	
		Filing Date	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	EH	Wigley et al. "Insulin Across Respiratory Mucosae by Aerosol Delivery" <i>Diabetes</i> 20:552-556 (1971)
	EI	Yamamoto et al. "Absorption Enhancement of Intrapulmonary Administered Insulin by Various Absorption..." <i>J. Pharm. Pharmacol</i> 46:14-18 (1994)
	EJ	Yoshida et al. "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form" <i>J. Pharma. Sci.</i> 68:670-671 (1979)
	EK	Zingg et al. "Transphatic Absorption and Biliary Excretion of Insulin" <i>Can. J. Physiol. Pharmacol.</i> 65:1982-1987 (1987)
	EL	Zinman "Medical Intelligence - The Physiologic Replacement of Insulin" <i>N. Engl. J. Med.</i> 321:363-370 (1989)

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